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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,261	07/23/2001	Victor G. Matassa	0380-P02370US0	7044

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
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PHILADELPHIA, PA 19103-2307

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,261	MATASSA ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,17 and 29 is/are rejected.
- 7) ☒ Claim(s) 2-16, 18-25,28 and 30-31 is/are objected to.
- 8) ☒ Claim(s) 1-25 and 28-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status Of Claims

The preliminary amendment filed January 4, 2002 has been entered.

Claims 26-27 were canceled; **Claims 5, 7, 9, 11, 15-17, 24, 28-30** were amended; and **claim 31** was added. **Claims 1-25 and 27-31** are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, **Claims 1-25, 28 and 31** drawn to an oligopeptide and a pharmaceutical composition, classified in Class 514, subclass 016. and **Claim 29**, drawn to a method of Hepatitis C treatment, classified in Class 514, subclass 016. **Claim 30** drawn to a method of production of a compound, classified in Class 514, subclass 016.

2. This application contains claims directed to the following patentably distinct oligopeptides of the claimed invention: In claims 1, 7, 13 and 18 the presence of general structure formulas and the ability to substitute a variety of amino acids and side chain moieties in each position has given rise to a multitude of oligopeptides. Depending on the substituted amino acids and side chain moieties the characteristics of the resulting oligopeptides will vary in regards to structure and activity- specifically in relation to protease inhibitory activity. Each one of these oligopeptides is patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single disclosed amino acid and side chain moiety for each position in the general oligo-peptide formulas [ie, define Y-B-A-X (claim 1), Y-B-A'-X' (claim 1), Z-F-E-D-C-B-A-X (claim 7), Z-C-B-A-X" (claim 13), Z-F-E-D-C-B-A-X (claim 18),

or Z-F-E-D-C-B-A'-X' (claim 18)] that is searchable : for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the amino acid and side chain moiety format for each position in the general oligopeptide is set forth as a series of alternatives.

Applicant is advised that a reply to this requirement must include an identification of the oligopeptide: that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is required under 35 U.S.C. 121 to elect one oligopeptide which defines each one of these structure formulas, Y-B-A-X (claim 1), Y-B-A'-X' (claim 1), Z-F-E-D-C-B-A-X (claim 7), Z-C-B-A-X" (claim 13), Z-F-E-D-C-B-A-X (claim 18), or Z-F-E-D-C-B-A'-X' (claim 18).

Should applicant traverse on the ground that the oligopeptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Sheldon on September 29, 2003 a provisional election was made without traverse to prosecute the invention of Group I with a further election of a core structure represented by compound 1d in

table 1, page 73. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

The current application filed on July 23, 2001 claims priority to PCT/GB99/01824 filed on June 9, 1999, which in turn claims priority to a foreign application, United Kingdom 9812523.0 filed on June 10, 1998. A certified translation of foreign document United Kingdom 9812523.0 has been provided.

Information Disclosure Statement

An IDS has not been filed with this application.

Specification

The disclosure is objected to because of the following informalities (page 26, line 1, page 27, lines 1-4, page 29, 17-29, page 42, lines 7-10, page 44, example 1, pages 46-66, example 2-9, pages 73-76, table 1): Failure to comply with Nucleotide and /or amino acid sequence disclosures in patent applications MPEP rule & 1.821(d). Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (C) of this section, reference must be made to the sequence by use of

the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or the claims of the patent application.

Appropriate correction is required.

Claim Objections

Claim 1 objected to because of the following informalities: colon missing at the end of line 11, page 1. Appropriate correction is required.

Claim 21 objected to because of the following informalities: colon missing at the end of line 1 page 100. Appropriate correction is required.

Claims 2-16, 18-25, 28 and 31 are objected to because they depend from rejected base claims.

Claims 1-12 and 18-19 are objected to because of the following informalities: These claims cite a general structure formula that allows for the presence of peptides that consist of four or more naturally occurring amino acids. In such an instance there is a failure to comply with Nucleotide and /or amino acid sequence disclosures in patent applications MPEP rule & 1.821(d). Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (C) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or the claims of the patent application. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 17, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** line 15 the word hydrocarbyl is indefinite because it is misspelled. The correct spelling is hydrocarbon.

In **claim 17**, the amendment does not specify which claim “ a tripeptide according to” is referring to. The applicant has only stated the word “claim” and has not provided a specific claim number.

In **Claim 29** HCV needs to be spelled out in the first instance of use. Also in **claim 29**, the word “preventing” is indefinite. In this claim applicant has only provided methods for treating or ameliorating.

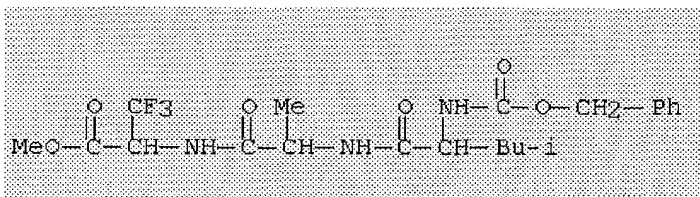
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

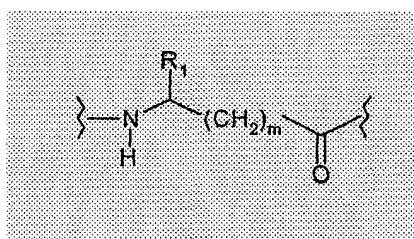
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

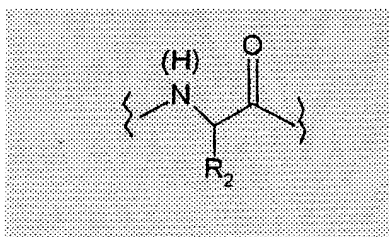
Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoss, E. et. al. . Hoss, E., et al. teach [Journal of Fluorine Chemistry (1993) , V.61 (1-2) , pages 163-170] the following structure:



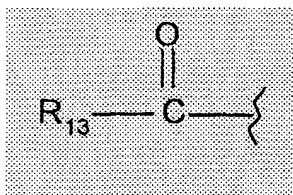
Claim 1 recites a structure according to the compound Formula II, with the following limitations; m may be 0, A' is an amino acid residue of formula:



R₁ may be a fluorine-substituted hydrocarbon side chain containing 1 carbon atom, B is a naturally or non-naturally occurring amino acid residue of formula:



R₂ may be a C₁-C₂₀ alkyl, y may be:



R₁₃ is an aliphatic or aromatic group containing 0-5 oxygen atoms. Thus Hoss et al. teach all the elements of **Claim 1** and this claim is anticipated under 35 USC 102(b).

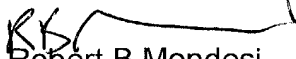
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.


Robert B Mondesi
Patent Examiner
Art Unit 1653
09-29-03


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